



4164-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2020-N-0008]**

#### **Patient Engagement Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a forthcoming public advisory committee meeting of the Patient Engagement Advisory Committee. The general function of the committee is to provide advice to the Commissioner, or designee, on complex issues relating to medical devices, the regulation of devices, and their use by patients. The meeting will be open to the public.

**DATES:** The meeting will take place virtually on October 22, 2020, from 10 a.m. Eastern Time to 5 p.m. Eastern Time.

**ADDRESSES:** Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at:

<https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Information on how to access the webcast will be made available no later than 2 business days prior to the meeting at [www.fdalive.com/PEAC](http://www.fdalive.com/PEAC).

**FOR FURTHER INFORMATION CONTACT:** Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66,

Rm. 5441, Silver Spring, MD 20993-0002, [letise.williams@fda.hhs.gov](mailto:letise.williams@fda.hhs.gov), 301-796-8398, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the *Federal Register* about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/advisory-committees> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications.

#### **SUPPLEMENTARY INFORMATION:**

*Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On October 22, 2020, the committee will discuss and make recommendations on the topic “Artificial Intelligence (AI) and Machine Learning (ML) in Medical Devices.” Specifically, we will discuss the composition of the datasets on which the software “learns”, components of the device information shared with patients, and factors that impact patient trust in the technology. Large clinical datasets are used to train and improve AI/ML algorithms, allowing transformational improvements in the diagnosis, clinical decision making, and treatment of patients. Devices using AI/ML technology will transform healthcare delivery by increasing efficiency of key processes in the treatment of patients. Health products powered by AI/ML are streaming into our lives, from virtual doctor apps to wearable sensors and drugstore chatbots to algorithms for detecting cancer in mammography and interpretations of chest X rays. Despite the rapid advancement and integration, AI/ML systems may have algorithmic biases, limited generalizability, and lack transparency in their assumptions based on potential limitations of training datasets. The recommendations provided by the committee will

address the importance of including various demographic groups in AI/ML algorithm development. The recommendations will also address the impact of the user interface and transparency including what information and how the information about the devices could be communicated to foster patient trust in the AI/ML devices.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background materials will be available at

<https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee>. Select the link for the 2020 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Oral presentations from the public will be scheduled on October 22, 2020, between approximately 1:30 p.m. Eastern Time to 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see FOR FURTHER INFORMATION CONTACT). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 22, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to

determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 24, 2020. Individuals who do not wish to speak at the open public hearing session but would like their comments to be heard by the committee may send written submissions to the contact person on or before September 30, 2020.

*Virtual Breakout Session:*

Individuals interested in participating in the virtual breakout scenario discussion will need to sign up to participate on or before October 8, 2020. The signup sheet, as well as, additional information pertaining to the virtual scenario discussion will be available at <https://www.fdalive.com/peac/>. Please note due to limited technology capacity, participation in the virtual breakout scenario discussion will be limited to 150 participants. The first 150 participants to sign up for the virtual breakout scenario discussion will receive a Zoom access link that will provide them with access to their assigned breakout room. Participants will receive the Zoom link no later than 2 days prior to the meeting. Individuals participating in the virtual breakout scenario discussion will only have access to Zoom during the time of the virtual breakout scenario discussion. Participants will need to sign out of the webcast and log into the Zoom at the time of the virtual breakout scenario discussion. Once the virtual breakout scenario discussion concludes participants will be signed out from Zoom and will need to log back into the webcast to participate in the remainder of the meeting.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due

to a disability, please contact AnnMarie Williams at [Annmarie.Williams@fda.hhs.gov](mailto:Annmarie.Williams@fda.hhs.gov), or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings> for procedures on public conduct during advisory committee meetings. Please be advised that, during the virtual scenario breakout discussions, FDA will prepare a summary of the discussion in lieu of detailed transcripts.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 21, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*